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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/684,599	10/05/2000	Ira Pastan	15280-259120US	2466

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EXAMINER	
HUNT, JENNIFER ELIZABETH	
ART UNIT	**PAPER NUMBER**
1642	9

DATE MAILED: 12/19/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/684,599	Applicant(s) PASTAN ET AL.	
	Examiner Jennifer E Hunt	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 17 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 17 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Acknowledgement is made of cancellation of claims 1-16 and 18 in paper number 4, filed 10-05-200. Claim 17 is pending in the application and considered herein.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim is drawn to a vaccine, but the terminology which described the vaccine is drawn to an active step of administrating an antigen. It is not clear if applicant intended to claim a vaccine product, or a method of treatment using a vaccine.

4. Further, claim 17 is unclear in the recitation of mesothelin derived antigen. The metes and bounds of a mesothelin derived antigen cannot be determined. It cannot be determined what would be considered a mesothelin derived antigen and what would not. Specifically, it is not clear what antigens would be considered mesothelin derived.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 17 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are broadly drawn to a vaccine for preventing or inhibiting mesotheliomas or ovarian tumors by administering a mesothelin derived antigen to a patient. Thus the claims are drawn to the extremely complex and unpredictable field of cancer vaccines and in vivo cancer treatment, and further encompass administration of anything which could be considered a mesothelin derived antigen to produce a therapeutic effect.

The specification discloses molecular cloning of CAK1 and that CAK1 is over expressed in some mesotheliomas, ovarian cancer, and squamous cell carcinomas. The specification provides no guidance or objective evidence that the mesothelin or a mesothelin derived antigen could be protective against mesotheliomas or ovarian cancer, or effective for treatment of such. No examples are provided, nor is guidance set forth that would demonstrate that a mesothelin derived antigen could or would function as a vaccine effective to inhibit or prevent mesotheliomas or ovarian cancer.

The prevention or inhibition of cancer is a complex method, requiring not only a sufficient immune recognition and reaction to prevent a disease from occurring to limit it's advancement, but the accurate prediction of populations which might be susceptible to specific cancers, such that appropriate patients would receive vaccines which recognized and prevented cancer which those patients might develop.

Thus in order to prevent cancer, a method would necessarily have to anticipate the cancer which the patient would develop, and be sufficiently immunogenic to prevent that cancer. Merely being immunogenic to provide some level of protection to a known antigen is a complex task, requiring specialized research. Further guessing which antigens might need to be protected against is well outside of the realm of routine experimentation.

In other words, the specification provides no exemplification of or guidance on how to use the claimed prevention or inhibition formulation. The goal of tumor vaccination is the induction of tumor immunity to prevent tumor recurrence and to eliminate residual disease, however, Ezzell (J. NIH Res. 1995 7:46) reviews the current thinking in cancer vaccines and states that tumor immunologists are reluctant to place bets on which cancer vaccine approach will prove effective in the long run (see the entire document, particularly the last paragraph) and further states that no one is very optimistic that a single peptide will trigger an immune response strong enough to eradicate tumors or even to prevent the later growth of micrometastases among patients whose tumors have been surgically removed or killed by radiation or chemotherapy (p. 48, para 6). In addition, Spitler (Cancer Biotherapy, 1995, 10:1-3) recognizes the lack of predictability of the nature of the art when she states that "Ask practicing oncologists what they think about cancer vaccines and you're likely to get the following response: 'cancer vaccines don't work'. Ask a venture capitalist of the director of product development at a large pharmaceutical company and you're likely to get the same response." (p. 1 para 1).

Thus demonstrating tumor antigen specificity in vitro cannot alone support the predictability of the method for preventing or inhibiting said tumor growth in vivo. The establishment and growth of a tumor is subject to variables beyond antigen specificity. The ability of a host to suppress and thereby prevent the tumor from establishing itself or advancing will vary depending upon factors such as the condition of the host, the type of tumor (rapidly proliferating or slowly proliferating) and the tumor burden. See Evans et al. 1999 who indicate that the goal of most vaccines is therapeutic efficacy- i.e. not sought to be developed to prevent the occurrence of cancer much as one would do with respect to infectious diseases (page 299, column 1 beginning of second section). Evans et al discuss various scenarios for combating cancer and it appears clear to one of skill in the art that cancer prevention is an unpredictable art and varies from tumor to tumor and the knowledge of the availability of protective tumor antigens. Evans et al conclude that (page 303, last column) - that the notion that cancer vaccines will replace standard therapeutic strategies in malignant disease still belongs to the realm of fiction.

Thus, in view of the contemporary knowledge in the art of the general lack of successful applications of vaccines for the inhibition and prevention of human diseases as discussed above, as well as the lack of sufficient guidance in the specification, one of skill in the art would be forced into undue experimentation in order to use the invention as claimed.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer E Hunt whose telephone number is (703) 308-7548. The examiner can normally be reached on Monday-Friday, 6-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0196.

Jennifer E Hunt
Examiner
Art Unit 1642

jeh
December 16, 2001

Sheela J. Huff
SHEELA HUFF
PRIMARY EXAMINER